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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/050,189

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Berish Rubin

Rubin-201-KGB

6280

7590 06/19/2008
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EXAMINER

MYERS, CARLA J

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

06/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/050,189	Applicant(s) RUBIN ET AL.	
	Examiner Carla Myers	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/27/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-7 and 14-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-7 and 14-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the amendment filed March 27, 2008. Applicant's arguments and amendments to the claims have been fully considered but are not persuasive to place all claims in condition for allowance.

The previous rejections of claims 8 and 13 under 35 U.S.C. 103(a) have been obviated by the cancellation of these claims.

2. Claims 3-7 and 14-17 are pending and have been examined herein. This action is made Final.

3. It is noted that the reply of March 27, 2008 does not include a complete or accurate record of the substance of the interview of January 3, 2008. See MPEP 713.04 and the Summary of Record of Interview requirements attached to the interview summary mailed January 15, 2008. A complete reply to this Office action must include a record of the substance of the interview of January 3, 2008.

Maintained Rejections

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3-6 and 14-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Slaughaupt (US 2005/0204409).

Slaughaupt (pages 10-12) teaches methods for detecting the presence of a mutation in the IKAP gene (referred to therein as the "IKBKAP" gene). In particular, Slaughaupt teaches methods which detect the presence of the T to C substitution at position 6 in the donor splice site of intron 20 and methods which detect the presence of a G to C transversion in exon 19, which results in an arginine to proline substitution at amino acid position 696 (referred to therein as nucleotide position 2397; see page 1, column 2). Slaughaupt teaches that the presence of each of these mutations is associated with the occurrence of FD (page 11). With respect to claims 5 and 6, Slaughaupt teaches that the nucleic acid to be analyzed is obtained by PCR amplification (page 4, column 2) and that the mutation may be detected by SSCP analysis (page 5, column 2). Accordingly, the method of Slaughaupt anticipates the claimed invention.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Slaughaupt (US 2005/0204409).

Slaughaupt (pages 10-12) teaches methods for detecting the presence of a mutation in the IKAP gene (referred to therein as the "IKBKAP" gene). In particular, Slaughaupt teaches methods which detect the presence of the T to C substitution at position 6 in the donor splice site of intron 20 and methods which detect the presence of a G to C transversion in exon 19, which results in an arginine to proline substitution at amino acid position 696 (referred to therein as nucleotide position 2397; see page 1, column 2). Slaughaupt teaches that the presence of each of these mutations is associated with the occurrence of FD (page 11). The reference also teaches that the nucleic acid to be analyzed is obtained by PCR amplification (page 4, column 2). Slaughaupt exemplifies primers for amplifying nucleic acids to detect the T to C substitution at position 6 in the donor splice site of intron 20 and the G to C transversion in exon 19 (see page 12, col. 1). Slaughaupt does not exemplify primers consisting of the sequences of presently claimed SEQ ID NO: 6-9.

However, Slaughaupt does teach the genomic sequence of the IKAP gene (see Figure 6 therein) and teaches that the cDNA for this sequence was known in the art at the time the invention was made (see page 10). Given the disclosure of Slaughaupt of the location of the 2 mutations within the IKAP gene, the disclosure of the genomic and cDNA sequences flanking the 2 mutations, and the disclosure of the use of PCR primers to amplify nucleic acid sequences containing the 2 mutations, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have generated additional primers, including the primers of present SEQ ID NO: 6-9, in order to have facilitated the detection of the intron 20 splice site and exon 19

Art Unit: 1634

mutations. Designing primers which are equivalents to those taught in the art is routine experimentation. The parameters and objectives involved in the selection of primers were well known in the art at the time the invention was made. Moreover, software programs were readily available which aid in the identification of conserved and variable sequences and in the selection of optimum primer pairs. The prior art is replete with guidance and information necessary to permit the ordinary artisan to design additional primers for the amplification of IKAP sequences containing the FD associated mutations in the intron 20 splice site and exon 19. As discussed above, the ordinary artisan would have been motivated to have designed additional primers for amplifying IKAP sequences so as to have provided additional primers which could be used to amplify and detect the FD mutations in the intron 20 splice site and exon 19. Further, the ordinary artisan would have had more than a reasonable expectation of success of obtaining additional primers for amplifying IKAP sequences. Thus, for the reasons provided above, and in the absence of evidence to the contrary, the primers of present SEQ ID NO: 6-9 and the use of these primers in methods for detecting the FD mutations in intron 20 and exon 19 would have been obvious to one of ordinary skill in the art.

Response to Arguments / Remarks

In the response of March 27, 2008, Applicants state that according to PAIR, the application underlying the '409 publication is not in condition for allowance. Applicants state that it is therefore permissible for Applicant to antedate the '409 publication based on Applicants 131 Declaration.

These arguments have been fully considered but are not persuasive. As discussed in the prior Office action and in the interview of January 3, 2008, an affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the reference is claiming the same patentable invention as that claimed in the present application. See MPEP § 2305:

Ordinarily an applicant may use an affidavit of prior invention under 37 CFR 1.131 to overcome a rejection under 35 U.S.C. 102(a) or 102(e). An exception to the rule arises when the reference is a patent or application published under 35 U.S.C. 122(b) and the reference has claims directed to the same patentable invention as the application claims being rejected. 37 CFR 1.131(a)(1). The reason for this exception is that priority is determined in an interference when the claims interfere. 35 U.S.C. 135(a). In such a case, the applicant must make the priority showing under 37 CFR 41.202(d) instead.

Since the '409 publication and this application are not commonly owned and because the application underlying the '409 publication has claims directed to the same patentable invention as the claims being rejected, the '409 publication can only be overcome by establishing priority of invention through interference proceedings. Regarding interference proceedings, Applicants attention is directed to MPEP 2304.02 and 37 CFR 41.202.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

Art Unit: 1634

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is 571-272-0747. The examiner can normally be reached on Monday-Thursday (6:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carla Myers/

Primary Examiner, Art Unit 1634